DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 13, 2014

DRAEGER MEDICAL SYSTEMS, INC.
BRYAN OVERTON
DIRECTOR, QA AND COMPLIANCE
3135 QUARRY RD
TELFORD PA 18969

Re: K133175
Trade/Device Name: Jaundice Meter JM-105
Regulation Number: 21 CFR 862.1113
Regulation Name: Bilirubin (total and unbound) in the neonate test system
Regulatory Class: I, reserved
Product Code: MQM
Dated: September 26, 2014
Received: September 26, 2014

Dear Mr. Overton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias -S

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k133175

Device Name
Jaundice Meter JM-105

Indications for Use *(Describe)*
The Jaundice Meter (JM-105) is a non-invasive transcutaneous bilirubinometer. It measures yellowness of subcutaneous tissue in newborn infants. The unit pro-vides a visual digital measurement that has been shown to correlate with serum bilirubin in newborn infants.

The device is intended for use in hospitals, clinics or doctor's offices under a physicians supervision / direction to assist clinicians in monitoring of newborn infants. The device is not intended as a standalone for diagnosis of hyperbilirubinemia. It is to be used in conjunction with other clinical signs and laboratory measurements.

Newborn infants whose JM-105 Jaundice Meter test results are indicative of hy-perbilirubinemia should be evaluated by their physician(s) for appropriate patient management. Specific neonatal patient Bilirubin levels should be confirmed by other methods, such as serum bilirubin, prior to treatment determinations.

The JM 105 is a prescription medical device
The JM 105 is not intended for home use.
The JM 105 may only be used at the sternum measurement site for Physician's office applications.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary
acc. to 807.92

Submitter's Name and Address: *Draeger Medical Systems, Inc*
3135 Quarry Road
Telford, PA 18969 USA

Contact Person: *Bryan Overton*
Phone: 215.660.2135
Fax: 215.721.5424

Date submission was prepared: November 6, 2014

Device Name:

Proprietary Name:	Jaundice Meter JM-105
Common Name:	Transcutaneous Bilirubinometer
Classification Name:	Bilirubin (total and unbound) in the neonate test system
Regulation Number:	21 CFR 862.1113
Product Code:	MQM
Class:	I, reserved

Predicate Devices:

510(k) Number	Device Name
K042522	Draeger JM-103 Jaundice Meter

Intended Use/Indications for Use

The Jaundice Meter (JM-105) is a non-invasive transcutaneous bilirubinometer. It measures yellowness of subcutaneous tissue in newborn infants. The unit provides a visual digital measurement that has been shown to correlate with serum bilirubin in newborn infants.

The device is intended for use in hospitals, clinics or doctor's offices under a physicians supervision / direction to assist clinicians in monitoring of newborn infants. The device is not intended as a standalone for diagnosis of hyperbilirubinemia. It is to be used in conjunction with other clinical signs and laboratory measurements.

Newborn infants whose JM-105 Jaundice Meter test results are indicative of hyperbilirubinemia should be evaluated by their physician(s) for appropriate patient management. Specific neonatal patient Bilirubin levels should be confirmed by other methods, such as serum bilirubin, prior to treatment determinations.

The JM 105 is a prescription medical device
The JM 105 is not intended for home use.

The JM 105 may only be used at the sternum measurement site for Physician's office applications.

Further information on application

Newborn infants whose Jaundice Meter test results are indicative of hyperbilirubinemia should be evaluated by their physicians for appropriate patient management. Specific neonatal patient bilirubin levels should be confirmed by other methods, such as serum bilirubin, before treatment determinations.

Limitations (Doctors Office Use)

Use only on infants up to 14 days of age.

For doctors' office application, use only the sternum location when taking measurements.

Please be aware, performance in doctors' offices may vary from performance in hospitals.

Device Description:
The Jaundice Meter is a non-invasive transcutaneous bilirubinometer. It measures yellowness of subcutaneous tissue in newborn infants. The unit provides a visual digital measurement that has been shown to correlate with serum bilirubin in newborn infants.

The JM-105 is a portable, hand held, battery powered device that includes a docking station with a built in reading checker. The JM-105 batteries can be charged using a battery charger or an optional USB cable.

The basic functionality including measurement of the JM-105 is equivalent to the JM-103. The display of the JM-105 has been improved (larger screen, touchscreen) and data storage and transmission functionality was added. The measuring probe, hardware, and software used to process the measurements are identical and therefore use the same measuring principle. The JM-103 and JM-105 determines the yellowness of subcutaneous tissue by using two optical paths to measure the optical density difference at two wavelengths. The measuring principle is further described in the "Principles of Operations" section of the Instructions for Use.

In addition to the features offered with the JM-103, the JM-105 provides the following.

- Internal memory up to 100 patient files
- Data transfer via HL7
- Easily mark & ID babies that need special attention with patient flagging
- Cost-efficient screening

There are no sterile or single-use components or accessories for the JM-105.

JM-105 Comparison to JM-103 Predicate

	Draeger JM-105	Draeger JM-103
Intended Use	The Jaundice Meter (JM-105) is a non-invasive transcutaneous bilirubinometer. It measures yellowness of subcutaneous tissue in newborn infants.	Same
Special condition for use	The Jaundice Meter is indicated for use in neonatal patients born >35 weeks gestation who have not undergone transfusion or phototherapy treatment.	Same
Measuring Method	Determines the yellowness of subcutaneous tissue by using two optical paths to measure the optical density difference at two wavelengths	Same
Measuring range	0.0 to 20.0 mg/dL or 0 to 340 µmol/L	Same
Accuracy (Clinical Data Standard Error of Estimate)	±1.5 mg/dL or ±25.5µmol/L (>35 weeks gestation)	Same
Light Source	Pulse Xenon Arc Lamp	Same
Sensors	Silicon photodiodes	Same
Power Source	2.4V, Special Ni-MH battery	Same
Protection type & level	Internally powered instrument, BF type	Same
Dimensions	56mm(W)×168mm(H)×45mm(D)	48mm(W)x154mm(H)x32mm (D)
Weight	203g including Ni-MH battery）	150g including Ni-MH battery）
Averaging function	Single, Avg. 1, 2, 3, 4 or 5	Same
Data Storage and Transmission	Yes	No

Substantial Equivalence:

The JM-105 and the above referenced predicate device have the same intended use. These devices are used by health care professionals as a screening device used on newborn infants to detect hyperbilirubinemia.

The measurement principle used in JM-105 is equivalent to that of the JM-103, and has been proven to be effective in screening infants > 35 weeks gestation.

Summary of Nonclinical Testing

This submission includes the results of testing for the JM-105 to demonstrate compliance to the product requirements. This includes electrical, mechanical, and software testing.

Testing was also performed to assess compliance to the following recognized consensus standards:

- IEC60601-1, Medical Electrical Equipment, Part 1: General Requirements for Safety
- IEC60601-1-2, Medical Electrical Equipment, Part 1-2: General Requirements for Safety Collateral Standard: Electromagnetic Compatibility

The test reports and results are located in section 10 of the submission.

Clinical Performance

The clinical performance data is provided in the JM-103 510(k) premarket notification (see k042522). The objective of the studies were to determine the accuracy and precision of transcutaneous bilirubin (TcB) measurements in infants neonates.

Hospital Study Design

Selection criteria

The patient selection criteria used for the studies included infants less than 30 days old and weighing greater than 1000 grams. Although the selection criteria was established as “less than 30 days of age,” the infants in the hospital studies were primarily NICU and newborn infants unless their medical condition required a longer duration of care. The test was performed on infants who were determined by their physician to require a serum bilirubin test.

Demographics of patient population

All patients meeting the above criteria were included in the study. There was significant effort to ensure sufficient representation of all skin pigmentation to verify that the JM-103 could be used across all populations with consistent results. The demographics of the patient population included Caucasian, African-American, East-Asian, Indian-Pakistani, and Hispanic infants.

Doctor’s Office Study Design

Studies were performed at two doctors’ office sites comparing JM-103 Total Calculated Bilirubin (TcB) to laboratory measured total serum bilirubin (TSB).

Selection criteria

The ages of the infants in the study ranged from approximately 24 hours to 7-10 days, with a mean of 3 days (at site 1) and 5 days (at site 2). The

test was performed on infants who were determined by their physician to require a serum bilirubin test.

Conclusions

Based on the data and information presented in this submission, the JM-105 is substantially equivalent to the currently legally marketed to predicate device referenced above.